4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Fecal Microbiota for Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID), are announcing a public workshop entitled "Fecal Microbiota for Transplantation." The purpose of the public workshop is to exchange information with the medical and scientific community about the regulatory and scientific issues associated with fecal microbiota for transplantation (FMT).

Date and Time: The public workshop will be held on May 2 and 3, 2013, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Preregistered participants will receive additional information on security procedures, parking, and public transportation with their email registration confirmation.

Contact Person: Chris Nguyen, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, email: CBERPublicEvents@fda.hhs.gov (subject line: FMT Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Chris Nguyen (see Contact Person) or email to CBERPublicEvents@fda.hhs.gov (subject line: FMT Workshop Registration) by April 18, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Chris Nguyen (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Fecal microbiota samples that have been isolated from healthy individuals are being investigated for use in the treatment of Clostridium difficile colitis. Published data from case studies and metaanalyses suggest that the use of fecal microbiota to restore gut flora may be an effective therapy in the management of refractory C. difficile infection. However, the efficacy of this intervention has not yet been demonstrated in controlled clinical trials. Such controlled trials are needed to demonstrate the safety and effectiveness of FMT products for C. difficile infection refractory to conventional therapy. FMT is also being considered as a treatment for inflammatory bowel disease, obesity, and other disorders, and controlled trials are needed in these settings as well.

Clinical studies to evaluate the safety and efficacy of FMT are regulated by FDA. FDA's primary objectives in reviewing an investigational new drug application are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phases 2 and 3, to help insure that the quality of the scientific evaluation of the product is adequate to permit an evaluation of safety and effectiveness. In addition, the complex nature of FMT products presents specific scientific and regulatory challenges.

To facilitate clinical development of FMT, CBER and NIAID are holding this workshop to provide a forum for the exchange of information, knowledge, and experience between CBER, NIAID, and the scientific-medical community.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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